Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Persons who are unable to attend, or who cannot be accommodated due to space limitations, are invited to provide written comments. A transcript of the meeting may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Elise A. Murphy or Richard A. Baldwin, Division of Field Science (HFC–141), 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, 301–443–3320, FAX 301–443–6388.

SUPPLEMENTARY INFORMATION: This dialogue will be accomplished by the submission of topics by participants. Topics should be submitted with a justification for their relevance and significance within the pharmaceutical industry. All topics will be considered for their inclusion into the meetings. After each meeting, a report will be prepared and made available to the public.

I. Background

On March 28, 1996, members of the pharmaceutical industry and FDA came together to informally discuss practical problems associated with laboratory aspects of the development and monitoring of pharmaceutical products. Prior to this, a series of meetings was held in the Mid-Atlantic region on December 15, 1994, February 24, May 1, and July 20, 1995. Following are the topics of meetings that were held in the Mid-Atlantic Region. Topics previously discussed locally can be revisited in the future if there is an interest.

A. Topics That Have Been Discussed Previously in the Mid-Atlantic Region

Topics that have been discussed previously are laboratory computer validation, laboratory automation and robotics, computer systems and subsystem validations, validation of software updates, vendor support of outdated software, integrity of data in electronic signatures, regulatory requirements for electronic signatures, bar coding technology, systems for sample tracking, installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ) of laboratory instruments.

On March 28, 1996, the meeting was convened by FDA's facilitator Richard A. Baldwin, Director, Division of Field Science. Gerald E. Vince, Director, Office of Regional Operations, gave the opening remarks and indicated that communication is beneficial to FDA and industry. Several presentations were given: Jeanne White from the Office of the Commissioner spoke about previous grassroots exercises and how successful they have been and Marie Urban, ORA 21 Coordinator, spoke on various initiatives by ORA in response to the Clinton Administration's National Performance Review and the Government Performance and Results Act of 1993. To conclude the presentations, James Farley, Director of the Philadelphia District Laboratory, gave background information as to how the discussion group came into existence.

An open dialogue was initiated as to how the discussion group should proceed and what the shared expectations should be for the group. The guiding principles and the items that emerged from the meeting are listed below.

B. Meeting Objectives (Guiding Principles)

One of the primary purposes of the discussion group is information sharing, which is vital for future success. At the March 28, 1996 meeting, it was suggested that FDA work with the trade associations to disseminate information, and utilize the associations as a vehicle for eliciting a priority list of topics from industry. Discussions will be open to all of the pharmaceutical industry and others so that everyone who is interested can participate. Another vehicle which was suggested was the use of the Internet and the FDA homepage for announcing the meetings and sharing information. Other suggestions for sharing information included focus groups, roundtable discussions, forums, and working groups.

The overall purpose of these meetings is to facilitate discussion and get a better understanding of expectations. The intent is a 360 degree understanding in context of flexibility—understanding the breath and depth of an issue from the various perspectives. There was an overall consensus that if there were a better understanding of each others situations, the agency and industry could work together to provide safer products to consumers.

II. Laboratory Issues: New Topics

Some laboratory issues and new topics that may be addressed at future meetings include the following: Identifying the acceptable ''best practices,'' research/quality assurance (QA), acceptable uses of technology, changes in technology, and pharmaceutical science-data integrity. FDA is interested in hearing whether there is interest in discussing these topics, as well as suggestions for other topics, by November 8, 1996.

Dated: October 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–27678 Filed 10–28–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health.

The Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health will provide advice and guidance to the Director, NIH, and other Federal officials in special areas of scientific programmatic need.

Unless renewed by appropriate action prior to its expiration, the Special Programs Emphasis Panel of the Office of the Director, National Institutes of Health will terminate two years from the date of establishment.

Dated: October 21, 1996.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 96–27632 Filed 10–28–96; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Notice of Meeting

Notice is hereby given of the meeting of the National Cancer Institute Board of Scientific Advisors on November 21–22, 1996 in Conference Room 10, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland.

This meeting will be open on November 21 from 8:30 am to approximately 5 pm and on November 22 from 8:30 am to adjournment at 1 pm. Agenda items will include: NCI Director's Report; Board operating procedures and representation at scientific meetings; presentation and discussion on how NCI distributes RPG funds and the RFA and contract support mechanisms; Board working group updates, presentation on the Cancer Genone Anatomy Project, and concept